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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,277	03/01/1999	KENJI KAWADA	32-248P	8984

7590

04/23/2002

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/23/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/214,277

Applicant(s)

KAWADA ET AL.

Examiner

Venkataraman  
Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

Applicants' response, which included cancellation of claims 38-39, 41 and amendment to claims 34, 37, 40, 45-46, 49 and 52, filed on 2/1/2002, is made of record.

Claims 34-37, 40, 45-49 and 52 are now pending.

In view of applicants' response the following apply.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-37, 40, 45-49 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of the term "prodrug" in claims 34-37, 40, 45-49 and 52 is deemed as indefinite. Prodrugs in general and as noted in specification, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrug is acceptable. However, the definition of various R<sub>1</sub> groups include such groups, namely esters, amides, alkoxycarbonyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.

#### ***Claim Rejections - 35 USC § 102***

In view of applicants' response, specifically pointing out that the provisos in instant claims would exclude prior art compounds cited in the previous office action all 102 rejections made in the previous office action have been obviated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goulding US 5,560,864.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kam Ming Chan et al. US 4,594,465.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. US 5,494,605.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiffenrath et al. US 5,487,845.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. US 5,417,885.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. GB 2,227,742.

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raynes et al. GB 198,743

Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al. GB 2,240,778

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Claims 34-36 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. GB 2,200,912.

Teachings of the 102 rejections made in the previous office action are incorporated herein.

While said compound doesn't anticipate the scope of instant claims, they are very closely related, having a methyl group on the aryl ring. However, compounds that differ only in having H vs Me in the aryl ring are not deemed patentably distinct absent evidence of superior or unexpected properties. Note *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Applicants' argument to overcome this rejection based on the discussion during an interview with applicants' counselor is not persuasive.

Applicants argue that the case laws are not applicable as they do not show situation of H vs methyl in aryl ring. The issue is hydrogen vs methyl analog not the exact structure. One trained in the art would know that substitution of hydrogen by methyl in most cases have same desired property. It should also be noted that one hand applicants' argue the compounds of the case law do not lend support to H vs methyl issue and one the other hand present properties of totally unrelated compounds for consideration. Furthermore, applicants' comparison of physical property of the compounds selected is irrelevant. Applicants have not shown that a in terphenyl system substitution of hydrogen by methyl would alter the utility. Coolings teaching does not

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show any variation of hydrogen by methyl would result in loss of liquid crystalline property. Furthermore, the references cited show variation in R<sup>1</sup> from alkyl to alkoxy to other groups without any loss of liquid crystalline property. Thus there appears to be no basis to assume that mere substitution of hydrogen by methyl in one of the other position would result in loss of desired property. Applicants need to show a comparative data showing unexpected/ superior property of instant compound vs prior art compound.

Hence the rejections are proper.

The following from the previous office action is again brought to applicants' attention:

Applicants should note that a large number of prior art citations were found in a sample search using CASONLINE and East search, in addition to those cited in the International Search Report. Examiner has applied only few of these prior art. Applicants are asked, in response to this action to clearly exclude prior art compound and indicate clearly the scope of the instant invention. Furthermore, the references cited in the International Search Report are not available to the examiner for consideration. Copies of these references are needed.

Applicants are again reminded that the references cited in the International Search report which includes several X references, are not available to the examiner.

This action is not made FINAL.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703)

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305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 5.30 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*V. Balasubramanian*  
Venkataraman Balasubramanian

4/21/2002